K051096

MAY 17 2005

510(k) Summary
(As required by 21 CFR 807.92)

A. Submitter Information

Submitter's Name:	St. Jude Medical
Address:	14901 DeVeau Place Minnetonka, Minnesota 55345-2126 U.S.A.
Telephone Number:	(952) 351-1453
Contact Person:	Mike Burnside
Date Submission Prepared:	28-April-2005

B. Device Information

Trade Name:	Apeel™ CS Plus Catheter Delivery System
Common or Usual Name:	Percutaneous Catheter Introducer
Classification Name:	Percutaneous Catheter Introducer (per 21 CFR Part 870.1340)
Device Classification:	Class II (per 21 CFR Part 870.1340) Panel – Cardiovascular
Predicate Device: Reference Device:	Apeel CS Catheter Delivery System Spyglass Angiographic Catheter
Device Description:	The Apeel™ CS Plus Catheter Delivery System includes a Peelable Introducer Sheath, Dilator, Cannulator, Detachable Hemostasis Valve with Side Port with 3-way Stopcock, Guidewire, Syringe, Needle, and 2 Valve Bypass Tools. The introducer kits are provided sterile, and are intended for single-use only.
Intended Use:	The Apeel CS Plus Catheter Delivery System is intended to provide vascular access including the coronary sinus and serve as a conduit for the delivery and support of other devices where minimizing blood loss is essential.

C. Comparison of Required Technological Characteristics

All technological characteristics of the Apeel™ CS Plus Catheter Delivery System are substantially equivalent to the predicate and referenced devices including product design, packaging, sterilization, and labeling.

D. Support of the Substantial Equivalence

St. Jude Medical considers the Apeel CS Plus Catheter Delivery System to be substantially equivalent to the predicate and referenced devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2005

Mr. Mike Burnside
Senior Regulatory Affairs Specialist
St. Jude Medical
14900 Minnetonka Ind. Rd.
Minnetonka, MN 55345

Re: K051096
Trade/Device Name: Apeel™ CS Plus Catheter Delivery System
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: II
Product Code: DYB
Dated: April 28, 2005
Received: April 29, 2005

Dear Mr. Burnside:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

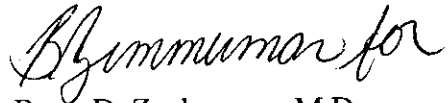
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051696

Device Name: Apeel™ CS Plus Catheter Delivery System

Indications for Use:

The Apeel CS Plus Catheter Delivery System is intended to provide vascular access including the coronary sinus and serve as a conduit for the delivery and support of other devices where minimizing blood loss is essential.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051696